BEFORE THE ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

In Re:	§	Docket No.
	§	EPA-HQ-OAR-2018-0746
Final Rule titled "National Emission	§	
Standards for Hazardous Air Pollutants:	§	
Miscellaneous Organic Chemical	§	
Manufacturing Residual Risk and	§	
Technology Review"	§	
	§	

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY'S PETITION FOR RECONSIDERATION

Pursuant to 5 United States Code ("U.S.C.") § 705 and 42 U.S.C. § 7607(d)(7)(B),[1] the Texas Commission on Environmental Quality ("TCEQ" or "commission") respectfully submits this Petition for Reconsideration ("Petition"), asking the United States Environmental Protection Agency ("EPA") to reconsider the adoption and implementation of the final rule regarding National Emission Standards for Hazardous Air Pollutants ("NESHAP"): Miscellaneous Organic Chemical Manufacturing ("MON") Residual Risk and Technology Review ("Final MON Rule"), published at 85 Federal Register (Fed. Reg.) 49084 (August 12, 2020). Specifically, the TCEQ requests that the Administrator reconsider his decision to adopt the Final MON Rule based on an outdated and demonstrably flawed Integrated Risk Information System ("IRIS") unit risk estimate ("URE") for ethylene oxide ("EtO"), as supported by the Final TCEQ Ethylene Oxide Carcinogenic Dose-Response Assessment[2] ("Final TCEQ EtO Assessment") and other recently available information.

I. BACKGROUND AND INTRODUCTION

On March 13, 2017, the U.S. District Court for the District of Columbia ("D.C. District Court") ordered the EPA to perform all acts or duties required by the Clean Air Act, ("CAA") 42 U.S.C. § 7412(d)(6) and (f)(2)[3] for twenty source categories, including Miscellaneous Organic Chemical Manufacturing, within three years of the date of the court order.[4] The EPA requested,

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[1] CAA § 307(d)(7)(B).
[2] TCEQ Ethylene Oxide Carcinogenic Dose-Response Assessment, Final, May 15, 2020, available at: https://www.tceq.texas.gov/toxicology/ethylene-oxide (Final TCEQ EtO Assessment).
[3] CAA § 112(d)(6) and (f)(2).
[4] see *California Communities Against Toxics, et al. v. Scott Pruitt*, 241 F. Supp. 3d 199 (D.D.C. 2017), Court Order, March 13, 2017.

and was granted, extensions of the deadline by the D.C. District Court. On August 12, 2020, the EPA published the Final MON Rule, and it became effective immediately. The CAA requires the EPA to assess the risk remaining after application of final air toxics standards, which is known as a residual risk assessment or review.

In the proposed MON rule, the EPA evaluated risk based on EtO as the primary contributor to risk for MON facilities[5] and adopted changes to address that risk.[6] The EPA evaluated risk associated with EtO emissions at MON facilities and found them to be unacceptable,[7] based exclusively[8] on the use of the most recently updated IRIS URE from their 2016 EtO assessment ("EPA 2016 EtO Assessment").[9] EtO is a gas used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents, and adhesives. EtO also is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment.[10] In 2018, EtO was being produced in the U.S. by 9 companies at 15 facilities in 11 locations, primarily in Texas and Louisiana.[11] Based on the EPA's 2017 National Emissions Inventory, Texas industry emits approximately 40% of the EtO in the U.S.[12]

Based on information that was not finalized and therefore was not available for submission to the regulatory docket during public comment, the URE from the EPA 2016 EtO Assessment is scientifically unsupportable and should not be used for risk assessment purposes in the Final MON Rule.

The Final TCEQ EtO Assessment provides additional scientific analyses that demonstrate the unreliability of EPA's URE, due to faulty model selection and inappropriate inclusion of breast cancer. Utilizing a URE that is demonstrably incorrect is indefensible both for the Final MON Rule as well as for the field of risk assessment itself since demonstrably unrealistic and inflated risk estimates serve to undercut public and scientific confidence in both present and

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[5] National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, Proposed Rule, 84 Fed. Reg. 69,182, 69,213 (Dec. 17, 2019).

[6] National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, Final Rule, 85 Fed. Reg. 49,084, 49,088 (Aug. 12, 2020).

[77]85 Fed. Reg. at 49,084, 49,088 and 49,097.

[8] 85 Fed. Reg. at 49,084, 49,098.

[9] United States Environmental Protection Agency (USEPA). 2016. Evaluation of the inhalation carcinogenicity of ethylene oxide (CASRN 75-21-8): In support of summary information on the Integrated Risk Information System (IRIS). EPA/635/R-16/350Fa. Washington, DC, U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. (USEPA 2016).

[10] EPA Hazardous Air Pollutant website for ethylene oxide: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/background-information-ethylene-oxide#what.

[11] Ethylene Oxide Frequently Asked Questions Document, American Chemistry Council, 2018: https://www.americanchemistry.com/EO/Ethylene-Oxide-Frequently-Asked-Questions.pdf

[12] EPA National Emission Inventory: https://www.epa.gov/air-emissionsinventories/2017-national-emissions-inventory-nei-data.

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future regulatory work. By contrast, the TCEQ's selected dose-response model, the standard Cox proportional hazards model, is demonstrated to be accurate for both the key National Institute for Occupational Safety and Health ("NIOSH") dataset as well as in the new validation study with the Union Carbide Corporation ("UCC") dataset, which was suggested by external peer reviewers. The new validation study confirmed the TCEQ model's robustness for predicting cancers for other populations and exposure scenarios such as those contemplated in the Final MON Rule. Additionally, a recent assessment supports the TCEQ Final EtO Assessment conclusion regarding EtO-induced breast cancer. The URE based on the EPA 2016 EtO Assessment is without sound scientific basis and should not be used in the Final MON Rule.

II. STANDARD OF REVIEW

The Administrator has the authority and a duty to reconsider the Final MON Rule.[13] Section 307 of the CAA directs that the Administrator "shall convene a proceeding for reconsideration" if two things are shown:

First, it was either impracticable to raise the objection during the comment period, or the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) . . . .[14] Second, the objection is of central relevance to the outcome of the rule – in this case, the August 12, 2020 Final Mon Rule.[15] The TCEQ's Petition meets both requirements.

While the TCEQ provided comments during the public comment period in the form of a revised draft EtO carcinogenicity assessment, it could not provide the assessment in final form, because, as discussed further in the Argument section below, the assessment was undergoing an additional, substantive external peer-review that was not completed until after the comment period closed. The University of Cincinnati Risk Science Center ("RSC") organized an independent peer review of the TCEQ's draft EtO assessment. The RSC was responsible for managing all aspects of the process, including selection of the expert reviewers. The TCEQ reviewed the proposed peer reviewers before selection for the sole purpose of providing additional conflict of interest information. The purpose of this peer review was to provide the TCEQ with expert opinions on the TCEQ inhalation cancer unit risk factor for EtO, in order to determine if it is scientifically adequate and appropriate for estimating cancer risk at ambient

[13] 42 U.S.C. § 7607(d)(7)(B), CAA § 307(d)(7)(B).
[14] *Id.*
[15] *Id.*

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(i.e., low-level) concentrations. The TCEQ response to the external expert comments resulted in a state-of-the-science final EtO carcinogenicity assessment.[16]

The peer-reviewers' report to the TCEQ was not finalized until April 30, 2020 and resulted in new and updated analyses that were included in the May 2020 Final TCEQ EtO Assessment. Submission of the Final TCEQ EtO Assessment during the public comment period (which ended on March 19, 2020) was, therefore, not just impracticable, it was impossible. The results of the external peer review revealed a likely shortcoming in the NIOSH study that led the EPA to incorrectly conclude that the breast cancer results were positive as part of the EPA 2016 EtO Assessment, and also prompted the TCEQ to conduct a model validation analysis for lymphoid cancer that further demonstrated the inaccuracy of the EPA's selected model. Thus, the Final TCEQ EtO Assessment revealed grounds for objection that arose after the period for public comment. As discussed in this Petition, the Final TCEQ EtO Assessment revealed new, additional scientific analyses that demonstrated that the URE was clearly unreliable, and therefore, unreasonable for use in the MON residual risk review. Analyses in the Final TCEQ EtO Assessment reveal that the URE value is simply not suitable for use in a residual risk assessment, which is fundamental to evaluating risk in the Final MON Rule. The TCEQ's objection to the EPA's use of the URE is, therefore, of central relevance to the Final MON Rule.

Because the grounds for the objections raised in this Petition were impracticable to raise during the public comment period, arose after the period for public comment, and are of central relevance to the outcome of the Final MON Rule, the Administrator must "convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed."[17] The Administrator also has the authority under its general rulemaking discretion to reconsider the Final MON Rule even if he concludes that the standards of CAA § 307(d)(7)(B)[18] have not been met.[19]

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[16] The RSC used best practices for peer review that reflect guidance from the Office of Management and Budget, the National Academy of Sciences, the EPA, and others. The RSC independently selected a group of six experts to provide a diversity and balance of relevant expertise and backgrounds. The group included at least two individuals who are expert in each of these key areas: environmental epidemiology; cancer dose response modeling; and cancer risk assessment/toxicology/mode of action. The experts were randomly assigned a number to allow candid opinions. The experts were asked 13 charge questions that specifically addressed open issues about the how the EtO assessment should be completed, including questions about model selection and validation, p-values and AIC calculations, and about the evidence that EtO causes breast cancer. The peer review report and the TCEQ's response to the report are available on the TCEQ's website at: https://www.tceq.texas.gov/toxicology/ethylene-oxide.

[17] *Id.*

[18] *Id.*

[19] Federal Administrative Procedures Act, 5 U.S.C. § 557.

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III. ARGUMENT

A. The EPA acknowledges the need for reconsideration of the Final MON Rule.

In the proposed MON rule, the EPA acknowledged that the TCEQ's draft assessment highlighted significant shortcomings in the EPA's URE derivation for EtO.[20] In the Final MON Rule, the EPA recognized the uncertainties in the URE[21] and noted that"[a]s always, the EPA remains open to new and updated scientific information, as well as new dose response values such as the TCEQ value, as they become available."[22] The EPA did not foreclose consideration of this and other "updated scientific information" after promulgation of the MON. In fact, the EPA left the door wide open. The external peer review of the TCEQ assessment was finalized April 30, 2020.[23] As discussed in this Petition, the EPA should reconsider the use of the IRIS URE in light of the peer reviewed Final TCEQ EtO Assessment.

B. The EPA 2016 EtO Assessment utilized an incorrect and unreliable model.

The Final TCEQ EtO Assessment incorporates recommendations by a formal external expert peer review organized by the University of Cincinnati RSC, and demonstrates that the model selected by the EPA (i.e., the linear two-piece spline model with knot at 1600 ppm-days) for derivation of its URE is inaccurate and therefore unsuitable for risk assessment for two reasons: it does not accurately predict lymphoid cancer deaths;[24] and it was based on incorrect Akaike information criteria ("AIC") and p-value calculations made by the EPA.[25]

The Final TCEQ EtO Assessment demonstrates that the EPA's selected dose-response model overestimates lymphoid cancer deaths, the cancer endpoint that primarily drives the URE, in the key NIOSH cohort by a statistically significant amount.[26] Additionally, a new model

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[20] 84 Fed. Reg. at 69182.
[21] "[D]ue to the inherent health protective nature of our risk assessment methods and certain uncertainties (Uncertainties regarding the equipment leak emissions, the uncertainties inherent in all risk assessments (i.e., the emissions dataset, dispersion modeling, exposure estimates, and dose-response relationships), and *the EPA's use of the 2016 unit risk estimate (URE) for ethylene oxide* (which is developed to be health protective).), the proposed risk assessment is more likely to overestimate rather than underestimate the risks..." [emphasis added]. 85 Fed. Reg. at 49094 and Footnote 6.
[22] 85 Fed. Reg. at 49098.
[23] University of Cincinnati Risk Science Center. 2020. Final Report for Letter Peer Review of Ethylene Oxide Carcinogenic Dose-Response Assessment Development Support Document. https://www.tceq.texas.gov/assets/public/implementation/tox/peer_review/eto.pdf.
[24] Final TCEQ EtO Assessment, Appendix 3, Sections A3.1, A3.2, and A3.3.3.
[25] Final TCEQ EtO Assessment, Appendix 6, Section A6.3.1.1.
[26] Final TCEQ EtO Assessment, Appendix 3, Sections A3.1 and A3.2.

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validation analysis prompted by the peer review report demonstrates that the EPA's model for the NIOSH dataset is also unable to accurately predict lymphoid cancer deaths in another group of workers (i.e., the UCC cohort),[27] revealing its unreliability for predicting cancers for other populations and exposure scenarios, and thus, its unsuitability for use in assessing risk.

In the Final TCEQ EtO Assessment, the dose-response models selected by the TCEQ and the EPA were further evaluated by applying the models obtained for the NIOSH cohort to an independent epidemiological data set that was not used to fit the models. Accordingly, a model that uses the parameters estimated using the lymphoid cancer mortality data from the NIOSH cohort can be validated by predicting the number of lymphoid cancer deaths in another cohort, namely the UCC cohort. The new peer review-recommended model validation analysis demonstrates that the TCEQ's selected dose-response model (i.e., the Cox proportional hazards model) derived for the key NIOSH dataset also accurately predicts lymphoid cancer deaths in the UCC cohort.[28] By contrast, the EPA's selected model (i.e., the linear two-piece spline model) derived for the key NIOSH dataset is demonstrated to be inaccurate, statistically significantly over-predicting the actual number of lymphoid cancer deaths observed in the UCC cohort. These new model validation analysis results for the UCC cohort are wholly consistent with those for the NIOSH cohort itself and support the robustness of the TCEQ's preferred model for predicting lymphoid cancer deaths for other populations and exposure scenarios. By contrast, these analyses provide no support for the EPA's selected model, as it is shown to be statistically significantly over-predictive in both the model validation analysis and for the very NIOSH dataset used to derive the model.[29]

Additionally, among other scientific issues with the EPA 2016 EtO Assessment, incorrect AIC values and p-values were calculated by the EPA. These values are standard statistical model fit criteria that play a central role in model selection, which in turn determines the URE. Consequently, the use of these incorrect values affected the EPA's choice of dose-response model and ultimately, the URE.[30] This is especially true since the EPA could not reconcile their model choice with EtO's carcinogenic mode of action,[31] as the TCEQ did for our selected model,[32] although mode of action is a main focus of the EPA carcinogenic guidelines.[33] The EPA

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[27] Final TCEQ EtO Assessment, Appendix 3, Section A3.3.3.
[28] Final TCEQ EtO Assessment, Appendix 3, Section A3.3.3.
[29] Final TCEQ EtO Assessment, Appendix 3.
[30] Final TCEQ EtO Assessment, Appendix 6, Section A6.3.1.1.
[31] The EPA acknowledged to the SAB that the mode of action information for EtO does not support an overall supra-linear dose-response, stating "the EPA is not aware of a mechanistic explanation" (p. I-29 of USEPA 2016; also see pp. I-34 and 4-71).
[32] Final TCEQ EtO Assessment, Chapter 4, Section 4.2.1.
[33] United States Environmental Protection Agency (USEPA). 2005a. Guidelines for Carcinogen Risk Assessment. (EPA/630/P-03/001B). Washington, D.C. United States Environmental

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Science Advisory Board ("SAB"), who conducted a peer review on the EPA's 2016 EtO Assessment, did not specifically review the EPA's AIC and p-value calculations.[34] However, the TCEQ's external expert peer review did evaluate the EPA's AIC and p-value calculations, concluding that they were incorrect and that the TCEQ had correctly calculated the values.[35] This new information would have been an important factor for the EPA to consider in deciding whether use of the URE was appropriate, since it contributed to selection of an inappropriate and inaccurate dose-response model. For example, one expert indicates "I do believe that TCEQ has identified a real problem with the EPA AIC and p-value calculations. The explanation of the issue and the resolution supplied in the DSD (Development Support Document)[36] seems appropriate. That is, I agree with TCEQ that the knot parameter in the spline models should be considered in the count of the parameters, that the AICs reported by EPA for those models are too low by a value of 2, and that the p-values should be computed using an approximation to a chi-square with 3 degrees of freedom."[37] Another reviewer also agreed with the TCEQ, stating "I consider that the location of the spline should be considered a parameter when evaluating fits of spline models, as long as the data were used in determining the knot, as it apparently was in EPA's model."[38] Yet another reviewer said "...the TCEQ arguments seemed reasonably convincing."[39] Although the AIC value for the TCEQ's selected model is slightly lower (i.e., slightly better) than the correct AIC for the EPA's selected model, the correct AIC and p-values are fairly similar for both the TCEQ's and the EPA's models, which increases the importance of the model accuracy analyses discussed above that clearly support the superiority of the Cox model selected by the TCEQ for predicting cancers in both the key NIOSH cohort as well as the model validation UCC dataset.

Protection Agency (USEPA). 2005b. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. (EPA/630/R-03/003F). Washington, D.C.

[34] The SAB did not comment on or examine the AIC issue identified by the TCEQ in Appendix H of USEPA 2016. The SAB only recommends less reliance on the AIC (e.g., pp. I-2 and I-9 of USEPA 2016), particularly its naïve use without other scientific considerations (pp. I-17 and I-18 of USEPA 2016), and discusses the fixing of some model parameters (as opposed to statistical fitting/estimating parameter values from the data as the EPA did) in a more general discussion of model parsimony (p. I-16 of USEPA 2016).

[35] TCEQ Response to External Peer Review Comments Received on the Ethylene Oxide Development Support Document, dated May 15, 2020; available at: https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/comments/eto/rtc%20peer%20review.pdf (TCEQ Response to External Peer Review Comments), Responses to charge question 6, pp. 45-53.

[36] TCEQ chemical assessments are called Development Support Documents.

[37] TCEQ Response to External Peer Review Comments, Expert 5 response to charge question 6, p. 49.

[38] TCEQ Response to External Peer Review Comments, Expert 6 response to charge question 6, p. 50.

[39] TCEQ Response to External Peer Review Comments, Expert 2 response to charge question 6, p. 46.

ED_005146_00000098-00007

C. The EPA also failed by using a URE for the MON that included EtO-induced breast cancer.

The EPA 2016 EtO Assessment relied on flawed data and included EtO-induced breast cancer in the development of the URE, but the weight of scientific evidence does not support the conclusion that EtO causes breast cancer. The Final TCEQ EtO Assessment found that the standardized incidence ratios and standardized mortality ratios across individual EtO studies of breast cancer are consistently not statistically significantly elevated, most being less than 1 (i.e., there was generally no relationship observed between EtO exposure and breast cancer incidence or mortality).[40] In conducting this weight of evidence evaluation, the TCEQ considered several studies not available at the time of the EPA 2016 EtO Assessment. For example, two recent meta-analyses of EtO studies that have examined breast cancer reported meta-relative risks of 0.97 (95% confidence interval = 0.80 - 1.18) ("Marsh et al., 2019")[41] and 0.92 (95% confidence interval = 0.84 - 1.02) ("Vincent et al., 2019").[42] The Marsh et al., 2019 study concluded, "Evaluations of workers exposed during sterilization processes do not support the conclusion that E[t]O exposure is associated with an increased risk of breast cancer."[43] Similarly, Vincent et al.. 2019 concluded, "Higher quality epidemiological studies demonstrated no increased risk of breast cancers."[44] Accordingly, the weight of epidemiological evidence does not support that EtO induces breast cancer, even in workers exposed to concentrations up to millions of times higher than typical environmental levels.

The Final TCEQ EtO Assessment also included additional information concerning the use of EtO-induced breast cancer as an endpoint. For example, an external expert peer reviewer of the TCEQ draft EtO Assessment indicated that without careful control in the analysis, the role of parity could result in a spurious positive association between EtO exposure and breast cancer risk.[45] Parity is "strongly related to risk of breast cancer (higher parity predicts lower risk) and strongly related to remaining in the work force to accrue greater exposure (more live births

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[40] Final TCEQ EtO Assessment, Chapter 3, Section 3.3.1.1.1.
[41] Marsh, GM, Keeton, KA, Riordan, AS, et al. 2019. Ethylene oxide and risk of lympho-hematopoietic cancer and breast cancer: a systematic literature review and meta-analysis. Int Arch Occup Environ Health. 92(7):919-939 (Marsh, et al. (2019)).
[42] Vincent, MJ, Kozal, JS, Thompson, WJ, et al. 2019. Ethylene oxide: cancer evidence integration and dose-response implications. Dose-Response: An International Journal October-December 1-17 (https://journals.sagepub.com/doi/10.1177/1559325819888317) (Vincent et al., 2019).
[43] Marsh, et al., 2019, page 937.
[44] Vincent et al., 2019, page 1.
[45] TCEQ Response to External Peer Review Comments, Expert 3 response to charge question 4, p. 36.

ED_005146_00000098-00008

predict cessation of employment)."[46] That is, "women with no or few children have elevated risk of breast cancer and work for longer periods of time, thus accruing greater cumulative exposure."[47] The reviewer commented that it is not clear that parity was effectively handled in the analysis for the NIOSH cohort, and that a parity bias is consistent with the finding that duration of exposure was more strongly associated with breast cancer incidence than cumulative EtO exposure. This is directly relevant to the breast cancer data relied upon by the EPA in the EPA 2016 EtO Assessment.[48] Combined with the overall lack of a supportive weight of evidence for EtO-induced breast cancer, this critical observation sows further doubt concerning bias in the specific breast cancer data that the EPA relied upon in 2016.[49] As an additional example, another external expert indicated, "It is clear that TCEQ chose not to derive their URE from the breast cancer data. Their analyses as described in the main text and in Appendix 6 support this as a reasonable choice."[50] Further, a new study was published in April 2020 that investigates cancer diagnoses in relation to 2013-2016 data from the National Health and Nutrition Examination Survey ("NHANES") on EtO blood levels in the general U.S. population ("Jain 2020").[51] Data from 3,955 adults were evaluated for the cancer analyses, of whom 1,973 were female (*see* Table 1 of the study). The author found no association between measured blood EtO and breast cancer in women (*see* the text and Table 4 of Jain 2020).[52]

Lastly, new evidence continues to support the TCEQ findings and does not support the EPA's conclusions regarding positive associations between EtO and breast cancer. The following figure from the just-released Agency for Toxic Substances and Disease Registry ("ATSDR") draft toxicological profile for EtO[53] is a good visual representation of how the weight of scientific evidence does not support that EtO causes breast cancer (and ATSDR does not conclude that it does), with almost all of the risk estimates having relative risks of less than 1 (i.e., falling to the left of the vertical line) and the 95% confidence limits including a relative risk of 1 for the other

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[46] TCEQ Response to External Peer Review Comments, Expert 3 response to charge question 4, p. 36.
[47] TCEQ Response to External Peer Review Comments, Expert 3 response to charge question 4, p. 36.
[48] 85 Fed. Reg. at 49098.
[49] Steenland, K, Whelan, E, Deddens, J, Stayner, L, Ward, E. 2003. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). Cancer Causes and Control. 14:531-539.
[50] TCEQ Response to External Peer Review Comments, Expert 2 response to charge question 4, p. 32.
[51] Jain, RB. 2020. Associations between observed concentrations of ethylene oxide in whole blood and smoking, exposure to environmental tobacco smoke, and cancers including breast cancer: data for US children, adolescents, and adults. Environmental Science and Pollution Research Available at: https://doi.org/10.1007/s11356-020-08564-z.
[52] *Id.*
[53] ATSDR Toxicological Profile for Ethylene Oxide Draft for Public Comment, dated September 2020, available at: https://www.atsdr.cdc.gov/ToxProfiles/tp137.pdf.

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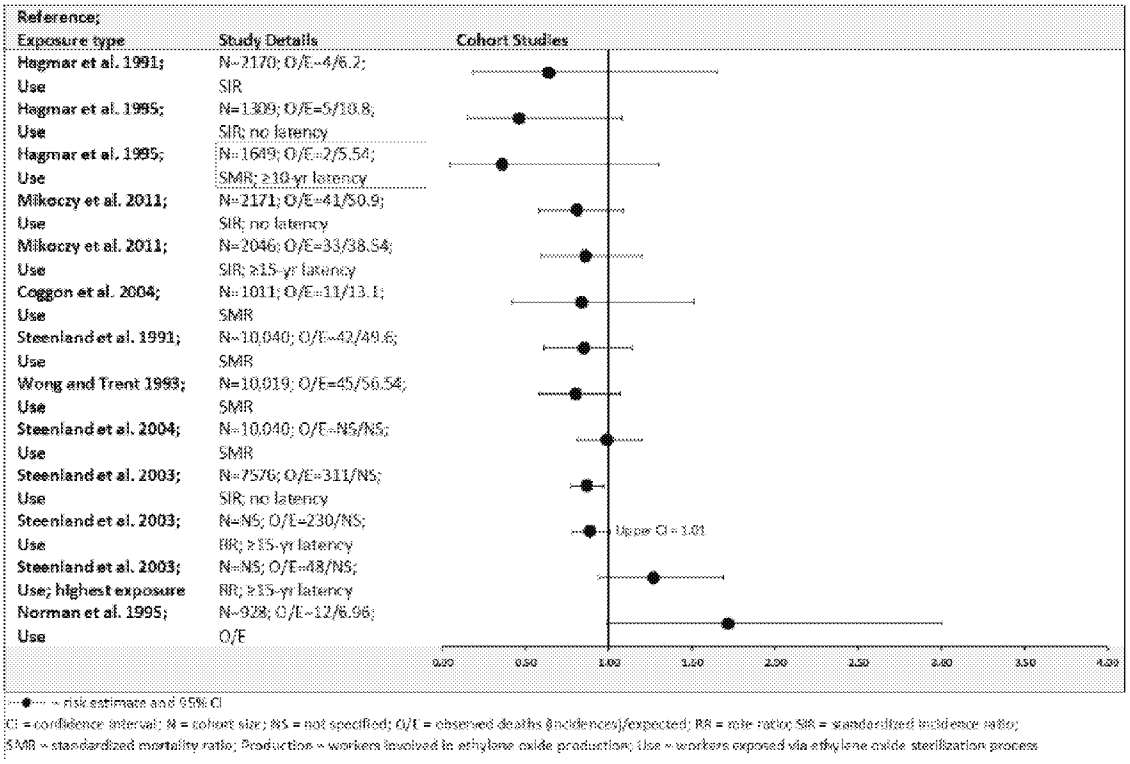
two studies. A relative risk of 1 or less than 1 indicates that there is no association between exposure to EtO and increase breast cancer incidence or mortality.

Figure 2-6. Summary of Epidemiological Studies Evaluating Associations between Inhaled Ethylene Oxide and Breast Cancer



Thus, the URE is scientifically flawed because it predicts excess risk that includes a cancer endpoint (i.e., breast cancer) assumed to be induced by EtO exposure that the available science does not adequately support.

The EPA 2016 EtO Assessment does acknowledge that the epidemiological evidence for EtO-induced breast cancer is less than conclusive, although the EPA decided to use EtO-induced breast cancer as a cancer endpoint despite this uncertainty. However, since new studies regarding EtO exposure and breast cancer further demonstrate a lack of scientific weight-of-evidence for EtO-induced breast cancer, as well as the significant potential for parity bias in the specific breast cancer data relied upon by the EPA, uncertainty for EtO-induced breast cancer has reached a level that merits reconsideration.

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D. The EPA must reconsider the Final MON Rule and must stay implementation of the Final MON Rule pending reconsideration.

In general, administrative reconsideration requires balancing the desirability of finality versus the public interest in reaching the right result.[54] Any argument that finality concerns somehow trump reaching the right result is without merit. The EPA was under a judicially established deadline for final rulemaking concerning the EtO residual risk and technology review for the MON NESHAP. But the EPA met its obligation when the Administrator signed the Final MON Rule. Thus, the only relevant consideration is the public interest in reaching the right result, and the public interest in reaching the right result weighs heavily in favor of reconsideration. The new information available as a result of the external peer review of the TCEQ draft EtO assessment and recently available information discussed in this Petition demonstrates several critical factors that the EPA did not consider in the Final MON Rule. This resulted in the EPA establishing EtO limits for the MON that are based on outdated and bad science. This is clearly not the right result and does nothing to further public health protections for this hazardous air pollutant.

Pending reconsideration to review the now final and peer reviewed Final TCEQ EtO Assessment, the Administrator should stay the application of the Final MON Rule. Under the Administrative Procedure Act ("APA"), "[w]hen an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review."[55] The EPA applies this standard to CAA cases.[56] The standard for such an administrative stay is significantly different from the standard for a stay used by the courts because it does not require a demonstration of irreparable harm. This is clear from the text of the APA:

> When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

Thus, the APA deliberately contrasts what is required for an administrative stay – "justice so requires" – and a judicial stay – "conditions as may be required" and "irreparable harm." Such differences must be given effect,[57] so there is no irreparable harm for an administrative stay.

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[54] *Civil Aeronautics Board v. Delta Air Lines, Inc.*, 367 U.S. 316, 321 (1961).
[55] 5 U.S.C. § 705.
[56] See Ohio: Approval and Promulgation of Implementation Plans, 46 Fed. Reg. 8581, 8582 n. 1 (January 27, 1981).
[57] [W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress act intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and citation omitted; alteration in original).

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IV. CONCLUSION AND REQUEST FOR RELIEF

As demonstrated by the Final TCEQ EtO Assessment, the URE used by the EPA in evaluating risk for the MON is incorrect and should be reconsidered. As discussed above, the URE resulted from significant errors in the EPA 2016 EtO Assessment, which significantly impacted the URE value by significantly overstating risk to a level beyond an ample margin of safety.

For the foregoing reasons, the TCEQ respectfully requests that the Administrator grant this Petition and promptly convene a proceeding for reconsideration of the Final MON Rule and stay its implementation pending reconsideration.

Respectfully submitted,

Toby Baker, Executive Director

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